

*REMARKS*

The Office Action dated May 22, 2009, and the references cited therein have been reviewed. Previously pending claims 1-34 stand rejected as obvious in view of the prior art.

Applicants have amended claims 1, 21, 24 and 26 to address the claim objections and section 112 rejections (indefiniteness). Moreover, each of the independent claims have been amended to more particularly distinguish the claimed invention (relating to generating a transfer function for a "catheter") from the prior art. In particular, each of the now pending claims now recites that a transfer function of a *catheter* is generated from backscatter ultrasound data *from within a vascular structure* AND the transfer function is based on an algorithm *incorporating an estimate of a tissue component of the backscattered ultrasound data*. The amendment is intended to emphasize that the present invention is directed to the determination of a *catheter's transfer function* (and thus an estimate of a tissue signal component in backscattered ultrasound data is used) using (1) backscattered ultrasound data from vascular tissue, and (2) an *estimate* of a tissue signal component.

Applicants request favorable reconsideration of the Office Action's grounds for rejection in view of Applicants' amendments and the remarks provided herein below. In particular, Applicant requests reconsideration of the Office Action's assertion that Rex's disclosure of a body part location-specific transfer function used to identify a location within a heart provides a sufficient reason for modifying Vince such that a *catheter's transfer function is rendered from backscattered ultrasound data from within a vascular structure and an estimate of a tissue component*.

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*Summary of the Rejections*

1. Claims 1-12, 21-24, and 26-34 are rejected under 35 U.S.C. §112 as being indefinite for failing to particularly point out the invention.

2. Claims 1, 3-16, 18-28, and 30-34 are rejected as obvious under 35 U.S.C. §103(a) over Vince et al., U.S. Patent 6,200,268 (Vince) in view of Rex U.S Patent 6,038,468 (Rex).

3. Claims 2, 17 and 29 are rejected as obvious under 35 U.S.C. §103(a) over Vince in view of Rex and Sieben U.S. Pat. No. 5,445,155 (Sieben).

Applicants traverse the grounds for each and every rejection for at least the reasons set forth herein below. Applicants address the specific rejections in the order they arise in the Office Action.

*Applicant's Specific Grounds for Traversing the Rejections**1. The Rejection of Claims 1-12, 21-24 and 26-34 as indefinite*

Applicants have amended claims 1, 21, 24 and 26 to address the clarity issues raised in the section 112 rejections. The claims have also been amended to address the claim objections (where appropriate).

*2. The Rejection of Claims 1, 3-16, 18-28, and 30-34 as obvious over Vince in view of Rex*

Applicants traverse the rejection of independent **claim 1** because the combined teachings of Vince and Rex do not disclose or suggest, to one skilled in the art at the time of the invention, generating a *catheter's transfer function* based on backscattered ultrasound data rendered from a location within a vascular structure.

Applicants' claimed invention is directed to generating (accurate) ultrasound response data for vascular tissue. In particular, the claimed invention is directed to calculating response data based upon received backscattered data and a transfer function determined for a *catheter*. See, Specification, page 1, line 26 to page 2, line 2. Determining the *catheter's transfer function* is based upon backscattered ultrasound signals received by an ultrasound probe while the probe is located within a vascular structure (e.g., blood vessel). Moreover, as further clarified by the current amendments, an estimate of the catheter's transfer function is calculated based upon "an algorithm incorporating an estimate of a tissue component of the backscattered ultrasound data." See, Specification, page 6, lines 25-32; and page 8, lines 7-16.

Applicants' claimed invention differs from prior art systems (such as Vince) wherein a transfer function for a catheter is rendered. In particular prior art systems did not contemplate a solution for providing a *catheter transfer function* using backscatter signal data provided from within a vascular structure. Instead, as Applicants noted in their application, the catheter transfer function was rendered using backscattered ultrasound data rendered outside a vasculature (e.g., using a perfect reflector). See, Background, page 2, lines 3-10. The differences between the claimed invention and prior art systems cannot be bridged by the irrelevant disclosure of a completely different type of "transfer function" disclosed in Rex. See, Rex, FIG. 3, col. 2, lines 8-34 ("transfer function" for identifying a location within a body part), and col. 3, line 60 to col. 4, line 14.

In particular, Rex's "transfer function" is *the measured quantity* (i.e., the desired output) of interest for further imaging analysis – as opposed to a signal component that needs to be *removed* from a received signal (e.g., Applicants' catheter transfer function). *See*, Rex, col. 4, lines 15 et seq. Rex relies upon variations in a disclosed *body part location-specific* "transfer function" to identify a location of the catheter within a vascular structure (i.e., heart). Variations between transmitted and received signals *caused by vascular tissue* (i.e., the heart wall) are what Rex refers to as the "transfer function." *See*, FIG. 3, Rex, col. 2, lines 8-14. In Rex each generated "transfer function" is compared to a pre-existing model to determine a location of a catheter within a heart. *See*, Rex, FIG. 3, col. 2, lines 8-34. Thus, Rex's "transfer function" *requires* obtaining an ultrasound signal from within a vascular structure since the "transfer function" is a measure of a particular location within the vascular structure. In contrast, Applicants' claimed *catheter transfer function* need not be rendered from backscattered signals from within a vascular structure – and, according to the prior art, are not rendered from such backscattered intravascular ultrasound signals.

One can readily observe from the above summaries (of the claimed invention and the prior art upon which the Office Action relies) that Rex has absolutely no relevance to determining a transfer function for a *catheter* and offers no solution for the inability in the prior art to generate a catheter's transfer function using a backscattered ultrasound signal generated from within a vascular structure. Applicants thus traverse the obviousness rejection of claim 1 (and each independent claim) in view of the absence of any proposed solution to the problem of removing an unknown tissue signal from backscattered ultrasound data (to determine a catheter's transfer function). Moreover, Rex cannot meet the shortcomings in the prior art in view of the clear inapplicability of Rex's body part location-specific "transfer function" that is used to determine a current location of a catheter within a heart – Rex's disclosed method of using a position-determining "transfer function" based on received signals never enable one skilled in the art to determine a *catheter's* transfer function based on signals received from within a vascular structure.

Moreover, Applicants traverse the rejection of independent claims 13 and 26 for at least the reasons set forth for claim 1 since these claims have similar recited elements to those that are identified as not being disclosed by the combined teachings of Vince and Rex. Moreover Applicants traverse the rejections of each of the dependent claims for at least the

reasons set forth herein for claim 1 (13 and 26) from which each depends. However, Applicants note certain dependent claims for which further comment is appropriate.

#### **Claims 3 and 18**

Applicants traverse the rejection of claims 3 and 18 since the Office Action has not even provided a *prima facie* case of obviousness. Namely, the Office Action does not identify a teaching in Rex of an algorithm that is "time-invariant over small intervals." Applicant requests identification of such teaching in the event the rejection is not withdrawn.

#### **Claims 4 and 19**

Applicants traverse the rejections of claims 4 and 19 since Vince does not even carry out the claimed estimation of a transfer function, but rather generates an actual transfer function for the catheter using a perfect reflector.

#### **Claims 12, 16, 25 and 34**

Applicants traverse the rejections of claims 12, 16, 25 and 34 for at least the further reason that calculating multiple transfer functions of the type defined by the presently claimed invention (i.e., ones that are generated from within a vascular structure and are based upon an algorithm incorporating an estimate of a tissue component of backscattered ultrasound data) are beyond the teachings of BOTH Vince and Rex. In the event the rejection is not withdrawn, Applicants request provision of a reference supporting the assertion that performing multiple "in vivo" determinations of a catheter's transfer function is well known in the art (since neither contemplates such multiple determinations of *Applicants' claimed transfer function*).

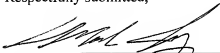
#### **3. Rejection of Claims 2, 17 and 29 as obvious over Vince in view of Rex and Sieben**

Applicant traverses the rejection of claims 2, 17 and 29 for at least the reasons set forth herein above regarding claims 1, 13 and 26 from which each depends.

*Conclusion*

Applicant respectfully submits that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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